AF/3743 # JFW

TRANSMITTAL OF APPEAL BRIEF (Large Entity)

Docket No.
2035.746

In Re Application Of: **Wisniewski et al.**

Serial No.	Filing Date	Examiner	Group Art Unit
09/881,909	**June 15, 2001**	**John K. Ford**	**3743**

Invention: **FREEZING AND THAWING VESSEL WITH THERMAL BRIDGE FORMED BETWEEN INTERNAL STRUCTURE AND HEAT EXCHANGE MEMBER**

TO THE COMMISSIONER FOR PATENTS:

Transmitted herewith in triplicate is the Appeal Brief in this application, with respect to the Notice of Appeal filed on **April 19, 2004**

The fee for filing this Appeal Brief is: **$330.00**

☒ A check in the amount of the fee is enclosed.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

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Signature

Dated: **June 10, 2004**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Wisniewski et al.	**Group Art Unit:**	3743
Serial No.:	09/881,909	**Examiner:**	John K. Ford
Filed:	June 15, 2001	**Appeal No.:**	
Title:	FREEZING AND THAWING VESSEL WITH THERMAL BRIDGE FORMED BETWEEN INTERNAL STRUCTURE AND HEAT EXCHANGE MEMBER		

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on June 10, 2004.

Brett M. Hutton
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Date of Signature: June 10, 2004

To: Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Brief of Appellant

Dear Sir:

This is an appeal from a final rejection, dated February 24, 2004, rejecting claims 1-55, all of the claims pending in the above-identified application.

Real Party In Interest

This application is assigned to **Integrated Biosystems, Inc.** by virtue of an assignment executed on August 28, 2001 by the co-inventors and recorded with the United States Patent and Trademark Office on reel 012257 and frame 0519. Therefore, the real party in interest is **Integrated Biosystems, Inc.**

Related Appeals and Interferences

To the knowledge of the appellant, appellant's undersigned legal representative, and the applicants, there are no interferences which will directly affect or be directly affected by or having a bearing on the Board's decision in the instant appeal. There are, however, two other appeals that may be directly affected by or have a bearing on the Board's decision in the instant appeal. All of these appeals involve the same Examiner. These appeals involve the following applications:

Serial Number No. 08/895,936, notice of appeal filed April 19, 2004.
Serial Number No. 09/881,909, notice of appeal filed April 19, 2004.

Status of Claims

This patent application was filed on June 15, 2001 as a continuation application of U.S. Application Serial No. 09/895,777, which was abandoned. As filed, this application included fifty-five claims, of which two (2) were independent claims (i.e. claims 1 and 30).

In an initial Office Action dated February 26, 2003, claims 1-55 were subject to an election requirement. The Examiner considered the application to be directed to twelve or more patentably distinct species of the claimed invention. In this same Office Action, claims 1-5, 7-10, 12-34, 36-37 and 39-55 were rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over the 1992 Wisniewski and Wu article or the 1986 Kalhozi and Ramadhyani article; claims 1-5, 7-

10, 12-34, 36-37 and 39-55 were rejected under 35 U.S.C. §103(a) as being unpatentable over the 1992 Wisniewski and Wu article or the 1986 Kalhozi and Ramadhyani article, and further in view of U.S. Patent No. 3,550,393 to Euwema ("Euwema"), U.S. Patent No. 5,535,598 to Cothern et al ("Cothern"), U.S. Patent No. 2,114,642 to West ("West"), U.S. Patent No. 1,874,578 to Morrison ("Morrison") and JP 57-58087 to Nakao ("Nakao"); claims 1-5, 7-10, 12-34, 36-37 and 39-55 were rejected under 35 U.S.C. §103(a) as being unpatentable over any of the prior art as applied above and further in view of the conceded prior art discussed on page 1, line 22 to page 2, line 17 of the specification; claims 11 and 38 were rejected under 35 U.S.C. §103(a) as being unpatentable over any of the prior art as applied to claim 1 and 30 above and further in view of U.S. Patent No. 2,915,292 to Gross ("Gross") and 2,391,876 to Brown ("Brown"); and claims 6 and 35 were rejected under 35 U.S.C. §103(a) as being unpatentable over any of the prior art as applied to claims 1 or 30 above and further in view of JP 3-43390 to Nagashio ("Nagashio") and JP 6-64094 to Koerber ("Koerber"). In appellants' response dated May 8, 2003, appellant elected the species shown in figures 1 and 2 and amended claims 1 and 30. Appellant also submitted the Second Declaration of Richard Wisniewski to address the Examiner's request for the submission of additional prior art.

In a second and final Office Action dated February 24, 2004, the Examiner maintained his rejections set forth in the first Office Action, despite the arguments and claim amendments set forth by the appellant in its response dated May 8, 2003.

A Notice of Appeal to the Board of Patent Appeals and Interferences was filed on April 19, 2004. The state of the claims is therefore as follows:

Claims allowed:	None
Claims objected to:	None
Claims rejected:	1-55
Claims cancelled:	None
Claims withdrawn:	None

Appellant is appealing the rejection of claims 1-55.

Status of Amendments

Appellant proffered no response to the final Office Action dated February 24, 2004. The claims as set out in the Appendix include all prior entered amendments.

Summary of the Invention

Appellant's invention is directed to a thermal transfer system that includes a container for receiving a medium and a structure positioned in the container such that the structure segments the container into a plurality of compartments wherein a distal end of the structure is in close proximity to an interior surface of the container to allow formation of a thermal transfer bridge, by the medium, wherein heat is transferred from the distal end of the structure through said thermal bridge to the interior wall in response to the interior wall being actively cooled. In another aspect of the present invention, a heat exchange member is at least partially coupled to the structure and extending into the container wherein a distal end of the heat exchange member is placed in close proximity to an interior surface of the container to allow formation of a thermal transfer bridge, by the medium, wherein heat is transferred from the distal end of the heat exchange member through the thermal bridge to the interior wall in response to the interior wall being actively cooled.

Issues

1. Whether any of the cited prior art, either alone or in combination, render claims 1-55 unpatentable.

2. Whether appellant satisfied its duty under Rule 56.

Grouping of Claims

Appellant respectfully submits that the claims do not stand or fall together. For example, claims 11 and 38 are a separate group, claims 23 and 54 another separate group and claims 29 and 55 another separate group. Each separate group includes additional features that provide separate basis of patentability from the independent claims 1 and 30 respectively.

Argument

I. The Claims Are Patentable Over The Cited Prior Art

Claims 1-55 stand rejected over various combination of at least eleven (11) prior art references. However, as noted below, none of these references disclose or suggest the formation of a thermal transfer bridge such that "heat is transferred from the distal end of the structure through the thermal bridge to the interior wall" in response to the interior wall being "actively cooled", as required by all of the claims. Further, all of the references describe completely different method of processing products using completely different principles and there is simply no motivation or suggestion to support a combination of any of these references.

In fact, the Examiner, in addressing a similar limitation in a final Office Action issued for Application No. 08/895,936 (which is also being appealed), supports this conclusion that there is no motivation or suggestion to combine any of the cited references by admitting the following:

> The Examiner . . . does not believe that there is anyone who can model or calculate these temperature profiles without the aid of sophisticated computers and/or experimental work. . . .The processes of modeling natural convection and moving-front phase change occurring together with sub-cooling is, to the Examiner's knowledge, is state of the art or beyond the state of the art in numerical solutions on computers. See Final Office Action, Application No. 08/895,936, page 8.

It is respectfully submitted that these freezing phenomena are so complex that no human being including one with nearly 30 years of experience can accurately

> predict such results. Purporting to have such ability only diminishes ones credibility. See Final Office Action, Application No. 08/895,936, page 10.
>
> Thus, researchers, other than Mr. Wisniewski, state that accurate modeling of phase change heat transfer in tanks with finned element such as shown in Figure 3 of the K&R article can only be done by computers or by direct empirical measurement. See Final Office Action, Application No. 08/895,936, page 11.
>
> [T]he temperature distribution must either be measured or generated by very sophisticated computer programs, which have had their validity checked against measured data. See Final Office Action, Application No. 08/895,936, page 12.
>
> Mr. Wisniewski's guesswork even in declarative form is simply no substitute for real evidence. Neither he nor any other person on the planet is in a position to properly guess at the actual temperature distribution. See Final Office Action, Application No. 08/895,936, page 14.

Accordingly, the Office admits that even those of ordinary skill in the art cannot look at and simply combine the cited references and arrive at the desired result disclosed in the Specification and recited in the claims of the present invention without experimentation or the aid of a computer.[1] However, contrary to the Examiner's repeated accusations that appellants have conducted "thought experiments," the explanations, schematics and temperature distributions provided by Mr. Wisniewski accompanying the First and Second Wisniewski Declarations were supported by experimentation (e.g. see page 12 of the Specification) and knowledge, albeit limited memory, of the device disclosed in the 1992 Wisniewski and Wu publication clearly support his conclusion concerning the workings of these devices. Moreover, the Specification at page 12 clearly describes a simulation for the system recited in the claims of the present invention and provides the parameters of the simulation, including the temperatures of the fins, the coolant and the wall.

Therefore, the Office's combination of any of these references is improper based on its own admission and personal understanding of this field of art.

[1] However, the Examiner continues to ignore the disclosure in the Specification of the present invention which describes a simulation of the device conducted by Applicants (See Specification page 12) and that Applicants considered different gap sizes (See Specification page 6).

1. Claims 1-5, 7-10, 12-34, 36-37 and 39-55 Are Patentable over the 1992 Wisniewski and Wu article

Claims 1-5, 7-10, 12-34, 36-37 and 39-55 stand rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over the 1992 Wisniewski and Wu article.

Each of the claims recite the formation of a "thermal bridge" such that "heat is transferred from said heat transfer member from said distal end of the structure through said thermal bridge to said interior wall" in response to the interior wall being "actively cooled." In order for a thermal bridge to form, the claims recite that the distal end of the structure positioned in the container must be in "close proximity" to the interior surface of the container. Thus, a "thermal bridge" is not merely "any area where a thermally conditioned surface is in greater proximity to another surface", as suggested by the Examiner. Rather, a "thermal bridge", as claimed, requires heat to be transferred therethrough in a particular way, i.e. from the heat transfer member to the interior wall, and the distal end of the structure must be in close proximity to the interior surface of the container. This heat transfer results in a downward temperature gradient from the heat transfer member to the interior wall of the vessel, when the interior wall is actively cooled.

In support of the rejection, the Examiner relies on his characterization of an "expansive definition" given to the term "thermal transfer bridge"[2] in the specification on page 4, line 3 through page 5, line 16. See Final Office Action, pg. 14. Further, the Examiner states that he does not see either in the specification or claims any limitation on the term thermal bridge that requires it to have a downward temperature gradient from the heat transfer member to the interior wall. Id. at 15.

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[2] Notably, unlike the final Office Action issued for U.S. Application Serial No. 08/895,936, the Examiner did not reject the claims under 35 U.S.C. §112, second paragraph, because the term "thermal bridge" was ambiguous.

However, the Examiner completely ignores the recitation in the claims requiring that heat is transferred from the distal end of the structure through the thermal bridge to the interior wall and that the interior wall is "actively cooled" and that the distal end of the structure is in "close proximity" to the interior surface of the container. Further, the Specification at page 10 and Figures 3 and 3b clearly show a thermal bridge having a downward temperature gradient when the interior wall of the container is actively cooled. For example, the temperature profile in Figure 3(b), which is reproduced below, shows heat transfer from the heat transfer member's distal end to the interior wall thus resulting in a downward temperature gradient from the heat transfer member to the interior wall of the vessel.

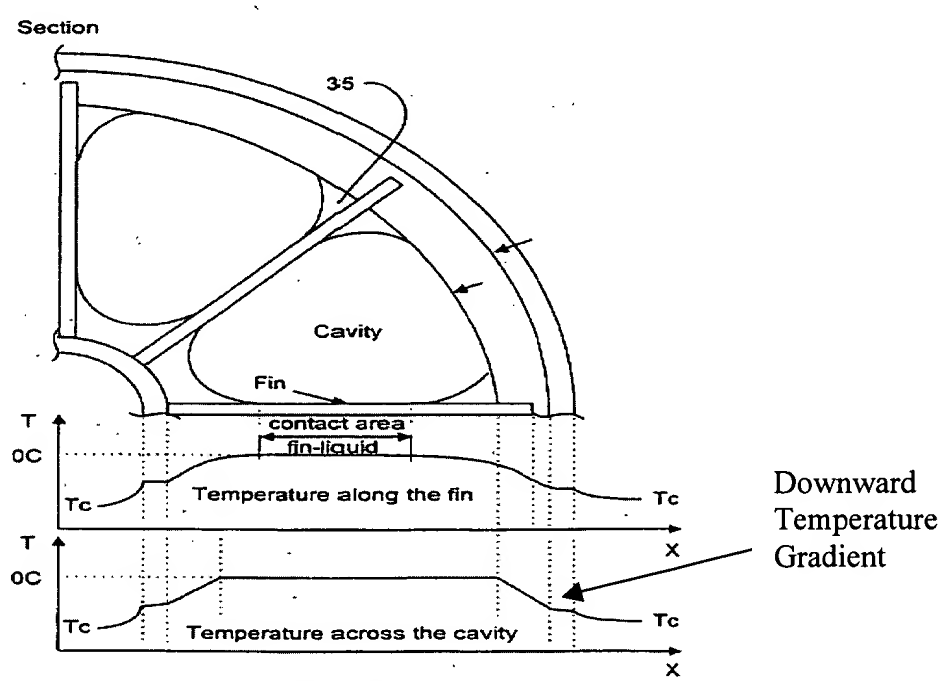

FIG. 3b

The Specification at pages 12 and 13 confirms that Fig. 3b occurs shortly after thermal bridges have begun to form. The Specification also enables persons of ordinary skill in the art to determine how the heat exchange structure must be positioned within

the interior cavity in order to form a thermal bridge by the medium between one or more of the heat transfer members and the interior wall. Specifically, the Specification provides at page 6, lines 8-14 the following:

> In general, the system should be constructed such that the distance to be bridged by the thermal transport bridge will be a function of the thermal properties of the medium and the system, manufacturing requirements and construction processes used to build the system, and other relevant parameters of the system and components used. The size of the gap to be filled by the bridge can be determined through simple trial and error.

The Specification further provides, on page 6, lines 23-27, clear examples of the size of the gap. Specifically, the Specification states that in one aspect of the present invention, the optimum gap is less than 2 inches, preferably less than 1 inch, even more preferably less than ¼ inch, and most preferably less than 1/8 inch.

In further support of the invention as claimed and to assist the Examiner in his understanding of the invention, appellants submitted two declarations by Richard Wisniewski during the prosecution of this and related applications in which he is also listed as the Examiner: (1) Declaration of Richard Wisniewski, dated January 23, 2002 ("First Wisniewski Declaration") and (2) Second Declaration of Richard Wisniewski, dated February 26, 2003 ("Second Wisniewski Declaration").

As supported by these declarations, Appellant respectfully submits that if, however, the gap between the heat transfer member and the interior wall is too large, a thermal transfer bridge will never form, even if the entire medium in the gap is frozen. (First Wisniewski Declaration, ¶6). If the gap is too large, then a location between the heat transfer member and the interior wall will have a higher temperature than the heat transfer member and the interior wall, even if the medium in the gap is frozen, and not a downward temperature gradient from the heat transfer member to the interior wall as claimed and depicted in Fig. 3(b) of the present application. (First Wisniewski Declaration, ¶8). Thus, if the gap is too large, heat is not transferred from the heat

transfer member through the medium in the gap to the interior wall. Rather, heat is transferred from the medium at a location in the gap to the interior wall and to the heat transfer member.

In other words, if the gap is too large, heat is being extracted from a location in the gap between the heat exchange member and the interior wall, not from the heat transfer member to the interior wall as required when a thermal bridge is formed. (First Wisniewski Declaration, ¶7). Thus, as compared to, for example, the downward temperature gradient from the heat transfer member to the interior wall shown in the temperature profile in Fig. 3(b), a temperature profile of a device, such as, for example, the device disclosed in the 1992 Wisniewski and Wu publication, would show the temperature gradually increasing after the fin to a location in the gap between the fin and the interior wall and then gradually decreasing towards the interior wall. (First Wisniewski Declaration, ¶7, Ex. B). In fact, even after the medium in the gap is frozen, the temperature at a location between the fin and the interior wall is still higher and heat is transferred from this location in the gap to both the fin and interior wall. (First Wisniewski Declaration, ¶¶8-9, Exs. C-D). Therefore, no thermal bridge wherein heat is transferred from the distal end of the heat transfer structure to the interior wall is formed by the device disclosed in the 1992 Wisniewski and Wu publication.

The Examiner fails to recognize the heat transfer characteristics of a "thermal bridge" as claimed and as described in the Specification, shown in the drawings and supported by the declarations submitted during prosecution. The Examiner provided no proof, other than his own personal knowledge, opinion and self-evident principles of heat transfer, to support his conclusion that a thermal bridge does not exist in the present invention or that the cited prior art inherently forms a thermal bridge, which is clearly contradictory to the appellant's disclosure. However, "[I]t is never appropriate to rely solely on 'common knowledge' in the art without evidentiary support in the record, as the principal evidence which the rejection is based." MPEP 2144.03. In the instant case, the Examiner's assessment of alleged basic knowledge and common sense is not based on

any evidence in the record and is simply not enough to support the rejection of the claims.

The Examiner has improperly referred to the term "thermal bridge" as an "ice bridge" since the beginning of prosecution and in other related applications. Specifically, the Examiner suggests that a thermal bridge of ice will inherently form [in the device disclosed in the 1992 Wisniewski and Wu publication] between the tip of the heat transfer fins and the interior of the container because they are the closest points to one another and both are actively cooled by circulating cooled silicon oil. In support, the Examiner points to the Voorhees patent and his own rendition of the device disclosed in the 1992 Wisniewski and Wu publication on page 19 of the final Office Action. However, in each of these instances, the Examiner equates an ice bridge with ice that surrounds or builds up on, for example, the interior wall <u>and</u> heat transfer member and eventually joins in the gap between the two.

> Whether ice forms in single cakes about several freezing elements or forms in a single cake inclosing a plurality of such elements depends upon the spacing of the several freezing elements from each other. In the first instance of course, ice forms separately about each freezing element, but if these elements be close together the ice surrounding these elements will soon coalesce into a single cake; and after this has occurred freezing will go on from the surface of the combination cake so formed. (Voorhees, col. 2, line 97 to col. 1, line 5).

In this instance, the Examiner equates an ice bridge with ice that surrounds or builds up on, for example, the interior wall <u>and</u> heat transfer member and eventually joins in the gap between the two. However, ice build up on two surfaces that meet in the middle of the gap is not a "thermal bridge" as defined by the present invention and does not create a downward temperature gradient from the heat transfer member to the interior wall, as required by the claims. Whether ice forms in single cakes about several freezing elements or forms in a single cake inclosing a plurality of such elements depends upon the spacing of the several freezing elements from each other. In the first instance of course, ice forms separately about each freezing element, but if these elements are close

together the ice surrounding these elements will soon coalesce into a single cake; and after this has occurred freezing will go on from the surface of the combination cake so formed.

Finally, the Examiner stated, numerous times throughout prosecution, his disbelief that a thermal bridge actually forms and requested experimentation, in the form of computer generated results" by the Applicants of the present invention and the device disclosed in the 1992 Wisniewski and Wu publication. With respect to the Examiner's request that Appellant conduct experiments and provide "computer generated results" on its own device, Appellant respectfully submits that the Specification describes a simulation for the system disclosed and provides the parameters of the simulation, including the temperatures of the fins, the coolant and the wall. The Fig. 3b is represented in the Specification as the result of this simulation.

> Figure 3b illustrates a simulation for the system shortly after thermal bridges 35 have begun to form. In this simulation, the material properties of 315 stainless steel were used for the container and the fins, and the coolant temperature was –45 °C. The temperature of the liquid was –0.2°C, the temperature of the fin in contact with the liquid was close to –0.2°C, and the temperature of the portion of the fin in contact with the frozen product was declining toward the temperature of the wall. The temperature of the wall was within 2-5°C of the temperature of the coolant. Specification, page 12.

Therefore, the Examiner request is unnecessary and cumulative to what was already provided and supported by the Specification. For some unknown reason, the Examiner has ignored the same.

With respect to the Examiner's request that appellant test the device disclosed in the 1992 Wisniewski and Wu publication, appellants have repeatedly informed the Examiner that this device is owned by Genentech, a customer in certain respects and a competitor in other respects. Although one of the inventors worked on this device back in the early 1990s as an employee of Genentech, he has provided as much information as

he remembers about the device in the form of declarations. Despite the fact that this inventor worked on this device over a decade ago, the Examiner continues to assert that he is not being forthcoming. However, there is absolutely no requirement for an applicant or their assignee to submit information that is unknown and/or not readily available. Accordingly, Applicants previous responses that this information and experimentation of a device they have no control over is unknown and not readily available should be considered and accepted as a complete reply to the Examiner's request. 37 C.F.R. §1.105(a)(3). Moreover, a demand or request for experimentation of an invention or a prior art device is not the type of information, listed in 37 C.F.R. §1.105(a), that an Examiner may require or request from an application or assignee. A further discussion of the Examiner's requests during the course of this prosecution will be discussed in more detail below.

Turning to the 1992 Wisniewski and Wu article, this article discloses a device having an internal heat transfer coil pipe with fins welded to the external surface of the coil pipe. A copy of this device is reproduced, for convenience, below:

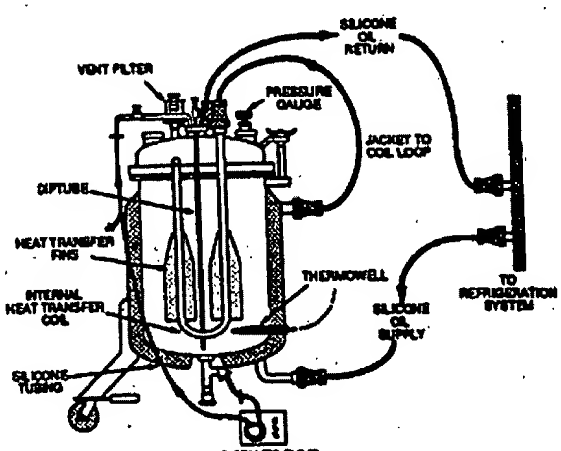

Figure 1. Freeze-thaw Vessel: Thawing Configuration

As shown, the fins attached to the pipe coil are very small and thin and were designed only to aid the freezing around the loop coil in order to increase the relatively small surface area of the loop pipe (e.g. adding more cold surface area). (Second

Wisniewski Declaration, ¶8). The distance depicted in this drawing reasonably represented the relationship between the distance between the fins and the interior wall. Id. Mr. Wisniewski declared that this distance was greater than 4 inches. (Second Wisniewski Declaration, ¶8). The outside of this device is cooled. Therefore, the temperature closer to the external wall from within the device decreases.

The First Wisniewski Declaration provides schematic representations of the freezing which would have occurred in the device disclosed in the 1992 article at a period of time before the medium between the fin and the interior wall of the device is entirely frozen along with a graph showing the temperature distribution along the radius of the vessel. (See First Wisniewski Declaration, Exhibits B, C). As depicted in these schematic representation and graph, the temperature in the gap between the fin and the interior wall increases and then decreases from the distal end of the fin to the interior wall. (First Wisniewski Declaration, ¶7). This temperature distribution occurs in part because the gap between the distal end of the fin and interior wall is too large. Id.

The Examiner attempts to describe the temperature distribution within the device disclosed in the 1992 Wisniewski and Wu article by claiming that the silicon coolant oil piped through the central cooling structure is at a higher temperature than biopharmaceutical that is along the vessel wall and, there it can never cool the contents in the central portion of the tank. See Final Office Action, page 15. Based on this, the Examiner concludes that the temperature of the distal edge of the fin will always be higher than at the interior side of the wall. However, the Examiner completely misunderstands the requirements for the formation of a thermal bridge and completely ignores the recitations in the claims. The claims of the present invention require the distal end of the structure to be in "close proximity" to an interior surface of the container to allow for the formation of a thermal transfer bridge. As supported by the Declarations of Richards Wisniewski, the distal ends of the fins disclosed in the 1992 Wisniewski and Wu articles are <u>not</u> in close proximity to the interior surface of the device as required by the claims of the present invention. Moreover, the Examiner's depiction of the device

disclosed in the 1992 Wisniewski and Wu article on page 19 of the final Office Action show that the temperature between the distal end of the fin and interior wall of the container must be higher since there is build up of frozen product on both surfaces that meet in the middle, and thus, no downward temperature gradient from the structure to the interior wall forms in this device. In fact, there is no discussion or suggestion in the 1992 Wisniewski and Wu publication about the thermal bridges where heat is transferred from the distal end of the structure through said thermal bridge to said interior wall as required by the claimed invention or the importance of thermal bridges in enhanced heat transport (See Specification at page 12, lines 9-16).

For the above reasons, appellant respectfully submits that the 1992 Wisniewski and Wu publication fails to explicitly or inherently teach or suggest the claimed invention.

2. Claims 1-5, 7-10, 12-34, 36-37 and 39-55 Are Patentable over the 1992 Wisniewski and Wu article and the 1986 Kalhozi and Ramadhyani article

Claims 1-5, 7-10, 12-34, 36-37 and 39-55 stand rejected under 35 U.S.C. §103(a) as unpatentable over the 1992 Wisniewski and Wu article and the 1986 Kalhozi and Ramadhyani article.

The 1986 Kalhori and Ramadyani article fails to overcome the deficiencies of the 1992 Wisniewski and Wu publication as applied against appellants' claimed invention. Specifically, the 1986 Kalhori and Ramadyani article fails to disclose or suggest the formation of a "thermal bridge" such that "heat is transferred from said distal end of the structure through said thermal bridge to said interior wall" in response to the interior wall being "actively cooled", as required by the claims. In fact, the 1986 Kalhori and Ramadyani article teaches a completely different method of freezing products, using completely different principles that, especially in light of the Examiner's comments concerning the need for the assistance of computer assistance to determine temperature

distribution, make combination of these references improper. Further, the 1986 Kalhori and Ramadyani article is not directed to the processing of different products than those processed in the 1992 Wisniewski and Wu article and, thus, fail to appreciate the problems associated with processing these products leading to no motivation to combine.

The 1986 Kalhori and Ramadyani article involves the investigation of the solidification of a paraffin[3] in a smooth, thin-walled metal cylindrical tank having an electrical strip heater wrapped around the upper part of the tank. The purpose of the investigation was to demonstrate that natural convection in the liquid phase plays a dominant role in melting and to a certain extent influences freezing. The investigation involves a comparison of the temperature distributions in the paraffin using a plain vertical cylinder in the tank and a vertical cylinder with fins, during cyclic melting and freezing. This cyclic cooling and heating generates convectional currents in the liquid phase of the medium. There is no disclosure or suggestion that the external tank walls are not actively cooled. In contrast, the vessel is wrapped with an electrical ban heater to warm the medium from the outside while the cylinder within is cooling it. Therefore, the temperature closer to the external wall from within the vessel increases, the temperature closer to the cylinder decreases, and heat transfer to the paraffin occurs from the cylinder.

The 1986 Kalhori and Ramadyani article simply concludes that the use of fins works better than no fins. However, this fact was already recognized in the 1992 Wisniewski and Wu publication as shown by the disclosure of the coil pipe having fins attached thereto. There is absolutely no disclosure or suggestion in the 1986 Kalhori and Ramadyani article of biopharmaceutical product or a discussion or recognition of the problems associated with processing biopharmaceutical product. Therefore, there is no motivation or suggestion to combine the 1986 Kalhori and Ramadyani article with the 1992 Wisniewski and Wu article because the 1986 Kalhori and Ramadyani article does

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[3] Paraffin is a white, waxy, odorless, tasteless solid substance consisting of a mixture of straight chais saturated hydrocarbon used to make, for example, candles, sealing preserving jars, waterproofing paper

not involve, or recognize the problems associate with processing, biopharmaceutical products.

There is also no motivation to combine the interior structure disclosed in the 1986 Kalhori and Ramadyani article with the container disclosed in the 1992 Wisniewski and Wu publication because the devices disclosed in both articles involve different principles of freezing. Specifically, the device disclosed in the 1992 Wisniewski and Wu article cools the container from the outside and the inside and the 1986 Kalhori and Ramadyani article heats the container on the outside while cooling the container inside. Therefore, contrary to the Examiner's suggestion, it would not be obvious to simply put the finned cylinder disclosed in the 1986 Kalhori and Ramadyani article in the tank disclosed in the 1992 Wisniewski and Wu publication because one of ordinary skill in the art would not be motivated to look towards the 1986 Kalhori and Ramadyani article to combine with the 1992 Wisniewski and Wu publication due to problems associated with processing biopharmaceutical products and the fact that the device in the 1992 Wisniewski and Wu article already uses fins and cools the device from the inside using the coil pipe.

Accordingly, Appellant respectfully submits that the 1986 Kalhori and Ramadyani Article fails to cure the deficiencies of the 1992 Wisniewski and Wu article. Therefore, withdrawal of this rejection and allowance of the claims is respectfully requested.

3. Claims 1-5, 7-10, 12-34, 36-37 And 39-55 Are Patentable Over The 1992 Wisniewski And Wu Article Or The 1986 Kalhori And Ramadhyani Article, And Further In View Of Euwema, Cothern, West, Morrison And Nakao

Claims 1-5, 7-10, 12-34, 36-37 and 39-55 stand rejected under 35 U.S.C. is §103(a) as unpatentable over the 1992 Wisniewski and Wu article or the 1986 Kalhori and Ramadhyani article, and further in view of Euwema, Cothern, West, Morrison and Nakao

None of these additional prior art references overcome the deficiencies of the 1992 Wisniewski and Wu publication and the 1986 Kalhori and Ramadhyani article as applied against appellants' claimed invention. Specifically, none of these additional prior art references disclose or suggest the formation of a "thermal bridge" such that "heat is transferred from said distal end of the structure through said thermal bridge to said interior wall" in response to the interior wall being "actively cooled", as required by the claims. Each of these references teach a completely different method of freezing products, using completely different principles that, especially in light of the Examiner's comments concerning the need for the assistance of computer assistance to determine temperature distribution, make combination of these references improper.

a. Euwema

Euwema discloses a cooling tank having a central tank for cooling a quantity of carbonated liquid, a refrigeration chamber surrounding the central tank, and a precooling tank surrounding and connected to the refrigeration chamber. Abst. The carbonated liquid that is processed by Euwema is located within central tank 4. There are no heat transfer structures positioned within cooling tank 4. Therefore, no thermal bridge is formed by the carbonated liquid because there is no gap created between the interior wall of the central tank 4 and a heat transfer member since no heat transfer member exist within the tank 4. Moreover, since there are no structures in the cooling tank 4, a thermal transfer bridge does not form to conduct heat into or out of the liquid in the cooling tank 4. In the final Office Action, the Examiner relies on the freezing of a cooling fluid located in an outer pre-cooling tank 8 and focuses on the formation of an "ice bridge." This precooling tank 8 has vanes 36 and 38 that are connected to the interior wall of a pre-cooling tank 8 and work to force the cooling fluid to be driven up and down as the fluid passes around the refrigeration chamber. The purpose of the fluid in the precooling tank is to provide relatively even cooling over the outer surface of the solidified precooling liquid. The cooling fluid in pre-cooling tank 8 and the refrigerant in refrigeration chamber 6 are not the desired product, i.e. carbonated liquid, to be cooled by the device disclosed in Euwema.

b. Cothern

Cothern is directed to a method and apparatus for freezing large blocks of a juice quickly. Cothern discloses vessel 30 having freezing members 110 extending downwardly into the liquid within the vessel. Refrigerant flows through the freezing members 110 to provide a heat exchange mechanism for removing heat from the liquid within the vessel. Since the freezing members have a lower temperature than the liquid within the vessel, e.g. between the tip of the freezing members and the interior wall, then the vessel disclosed in Cothern does not disclose a thermal transfer bridge because it cannot have a downward temperature gradient from the freezing member to the interior wall of the vessel, as required by the present invention. In fact, the vessel disclosed in Cothern has the reverse, i.e. an upward temperature gradient from the freezing members 110 to the interior wall of the vessel. Therefore, Cothern fails to disclose or suggest the formation of a thermal transfer bridge that conducts heat into and out of the medium.

c. West

West also fails to overcome these deficiencies. West discloses an apparatus for accelerating the production of frozen articles, such as, milk, sherbets, ice creams, puddings and whipped cream. Col. 4, lines 39-43. The West apparatus includes a cooling unit having an evaporator that provides a plurality of freezing units 4 adapted to receive and contain a refrigerant. The freezing units are stationary and project down into the freezing chamber 5. The freezing chamber 5 is filled with a predetermined amount of liquid to be frozen. During freezing, the refrigerant will be condensed in a condenser 10 and accumulated in the receiver 11. The compressor 9 is started and evaporation of the refrigerant within the evaporator 3 causes rapid freezing of the contents of the containers because of the direct heat conductivity between the freezing members 4 and the substance to be frozen. Again, similar to Cothern and Morrison discussed below, the liquids are cooled in West by a structure within the device. Since the freezing member 4 has a lower temperature than the liquid within the West freezing container 8, e.g. between the tip of the freezing members and the interior wall, then the device disclosed in West does not

disclose a thermal transfer bridge because it cannot have a downward temperature gradient from the freezing member to the interior wall of the vessel. Therefore, West fails to disclose or suggest the formation of a thermal transfer bridge that conducts heat into and out of the medium.

d. Morrison

Morrison is directed to a heat exchange device for use in heating or cooling liquids such as milk, or water or the like. Similar to Cothern, the liquids are cooled in Morrison by a structure within the device. This structure includes hollow blades 7 that communications with a vertical chamber 6 so that heat or cooling liquid circulates therethrough. There is no disclosure in Morrison that the walls of the container are "actively cooled." Since the hollow blades 7 and vertical chamber 6 have a lower temperature than the liquid within the Morrison device, e.g. between the tip of the freezing members and the interior wall, then the device disclosed in Morrison does not disclose a thermal transfer bridge because it cannot have a downward temperature gradient from the freezing member to the interior wall of the vessel. In fact, the Morrison device has the reverse, an upward temperature gradient from the freezing members 110 to the interior wall of the vessel. Therefore, Morrison fails to disclose or suggest the formation of a thermal transfer bridge that conducts heat into and out of the medium.

e. Nakano

JP 57-58087 to Nakano is directed to a container for a heat accumulating agent. The Nakano container has metallic plates inserted within the container. The heat accumulating agent 3 is fused due to heating, the heat of the fused part of the agent is transferred to the metallic plates 5 to heat the same. The arrows shown pointing to exterior surface of the container around its entire circumference appear to represent heat being applied to the exterior surface. With heat being applied to the outer surface of the container, there can be no downward temperature gradient from the tip of the metallic plates to the interior wall of the container because the temperature of the container wall is

considerable higher than the tips of the metallic plates that transfers heat from the heat accumulating agent 3. Therefore, Nakano fails to disclose or suggest the formation of a heat transfer bridge as required by the claims of the present invention.

The Examiner concludes that it would have been obvious to one of ordinary skill in the art to have extended the fins in the device disclosed in the 1992 Wisniewski and Wu article to "substantially the inner periphery of the container, leaving a small gap to permit the heat exchanger to be removed for cleaning. However, the 1992 Wisniewski and Wu publication teaches away from such an extension of the fins towards the interior walls. Specifically, the publication teaches that the heat transfer fins "were configured to divide the tank volume into compartments to decrease freezing and thawing time and to reduce cryoconcentration effects." See pg. 136, col. 1. Thus, the 1992 Wisniewski and Wu publication already teaches that the fins in the device aid in forming compartments and there is no motivation or suggestion in this publication to further extend the fins further towards the walls.

None of these references disclose or suggest the formation of a "thermal bridge" where heat is transferred from the distal and of the structure through the thermal bridge to the interior wall. Moreover, since all of these devices teach different methods and principles of processing where heat is transferred from the distal end of the structure through the thermal bridge to the interior wall materials, there is clearly no motivation or suggestion to combine. Accordingly, withdrawal of this ground of rejection and allowance of these claims are respectfully requested.

4. Claims 1-5, 7-10, 12-34, 36-37 And 39-55 Are Patentable Over Any Of The Prior Art As Applied Above And Further In View Of The Conceded Prior Art Discussed On Page 1, Line 22 To Page 2, Line 17 Of The Specification

Claims 1-5, 7-10, 12-34, 36-37 and 39-55 stand rejected under 35 U.S.C. §103(a) as unpatentable over any of the prior art as applied above and further in view of the conceded prior art discussed on page 1, line 22 to page 2, line 17 of the specification.

During prosecution, appellant submitted that the first two paragraphs in the Description of Prior Art section on page 2 of the specification refers to the device disclosed in the 1992 Wisniewski and Wu publication. (Second Wisniewski Declaration, ¶8). Therefore, as discussed above, this conceded prior art does not disclose or suggest the formation of a "thermal bridge" as required by the claims of the present invention.

The prior art described in the third paragraph of this section[4] refers to a device having ribs welded to both the core structure and the interior wall of the vessel. Such vessels can be used in storage devices for, e.g., paraffin. (Second Wisniewski Declaration, ¶9). During prosecution, appellants directed the Examiner to two prior art patents, U.S. Patent Nos. 2,441,376 to Stiening and 2,129,572 to Finnegan to show the type of devices mentioned in this part of the Specification. Since the ribs are connected to both the internal core and the interior wall of the vessel, no thermal bridge can be formed by the medium between a fin tip and the interior wall of the vessel (Second Wisniewski Declaration, ¶9). Heat transfer occurs only through the external wall of the vessel.

[4] The statement by the Examiner in the final Office Action that appellants "refused to provide a sketch" of this prior art device is without merit. Appellants directed the Examiner to a prior art references having similar features as discussed in this section. Clearly, it is not unduly burdensome to ask the Examiner to "imagine" the fins being secured to the interior wall of a device, which is completely irrelevant to the claims of the present invention because fins that contact the interior wall are not considered in close proximity to the interior wall and a thermal bridge cannot be formed "by said medium" as recited in the claims because there is no gap between the distal end of the structure and the interior wall of the container.

Accordingly, withdrawal of this ground of rejection and allowance of these claims are respectfully requested.

5. Claims 11 And 38 Are Patentable Over Any Of The Prior Art As Applied To Claim 1 And 30 Above And Further In View Of Gross And Brown

Claims 11 and 38 stand rejected under 35 U.S.C. §103(a) as unpatentable over any of the prior art as applied to claim 1 and 30 above and further in view of Gross and Brown.

As discussed above, none of the prior art references cited by the Office disclose or suggest the formation of a "thermal bridge" such that "heat is transferred from said distal end of the structure through said thermal bridge to said interior wall" in response to the interior wall being "actively cooled", as required by the claims. Each of these references teach a completely different method of freezing products, using completely different principles that, especially in light of the Examiner's comments concerning the need for the assistance of computer assistance to determine temperature distribution, make combination of these references improper. Further none of these additional references are directed to the processing of biopharmaceutical products and, thus, fail to appreciate the problems associated with processing these products and, thus, there is no motivation to combine with the 1992 Wisniewski and Wu article.

The Gross and/or Brown patents also fail to overcome these deficiencies. Gross discloses a heat exchanger apparatus for facilitating the transfer of heat through heat-conducting walls of the apparatus by the circulation of fluid heat-transfer medium in contact with the heat-conducting walls. Abst. The heat exchanger apparatus has a cavity defining heat-conducting wall 1 that houses a casing 10 formed of a flexible material with partitions 15 which are integral with the casing 10. Casing 10 is inserted into the cavity within the heat-conducting wall 1. Edges 16 of partitions 15 are resiliently pressed against the inner surface 2 of wall 1. Col. 4, lines 5-16. The "means forming spiral paths

on the outside of a tank" referred to by the Examiner in the Final Office Action (page 48) in Gross are brackets 216 or spacers 215 that assist in supporting the kettle, not baffles within the fluid flow path between a jacket and the exterior wall of the apparatus to define a spiraling path for fluid, as required by the claims.

Brown discloses a material treating tank to heat or cool plastic mixtures or fluid, for instance, in dairy processing and chemical plants. Col. 1, lines 10-13. The tank disclosed in Brown has a jacket surrounding the tank which facilitates the circulation of fluid heat exchange medium. There are no internal heat transfer structures contained within the tank. Therefore, a "thermal bridge" does not form between a heat exchange structure and the interior wall of the tank, as required by the claims of the present invention. Brown teaches a completely different method of freezing products, using completely different principles that, especially in light of the Examiner's comments concerning the need for the assistance of computer assistance to determine temperature distribution, make combination of this reference improper. Further Brown is not directed to the processing of biopharmaceutical products and, thus, fails to appreciate the problems associated with processing these products and, thus, there is no motivation to combine.

Accordingly, withdrawal of this rejection and allowance of the claims are respectfully requested.

6. Claims 6 And 35 Are Patentable Over Any Of The Prior Art As Applied To Claims 1 Or 30 Above And Further In View Nagashio And Koerber

Claims 6 and 35 are patentable over any of the prior art as applied to claims 1 or 30 above and further in view Nagashio and Koerber.

Nagashio and Koerber fails to cure the deficiencies of any of the cited prior art. Each of these references teach a completely different method of freezing products, using

completely different principles that, especially in light of the Examiner's comments concerning the need for the assistance of computer assistance to determine temperature distribution, make combination of these references improper. Further none of these additional references are directed to the processing of biopharmaceutical products and, thus, fail to appreciate the problems associated with processing these products and, thus, there is no motivation to combine with the 1992 Wisniewski and Wu article.

Accordingly, withdrawal of this rejection and allowance of the claims are respectfully requested.

Conclusion

For the reasons set forth above, reversal of the rejections and allowance of this application are respectfully requested.

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Respectfully submitted,

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APPENDIX

CLAIMS FOR APPLICATION SERIAL NUMBER 09/881,909

1. A thermal transfer system, comprising:

a container for receiving a medium;

a structure positioned in the container such that the structure segments the container into a plurality of compartments wherein a distal end of the structure is in close proximity to an interior surface of the container to allow formation of a thermal transfer bridge, by said medium, wherein heat is transferred from said distal end of the structure through said thermal bridge to said interior wall in response to said interior wall being actively cooled.

2. A thermal transfer system as in claim 1 including:

a heating or cooling device coupled to and provides heating or cooling of the container.

3. A thermal transfer system as in claim 1 including:

a heating or cooling device coupled to and provides heating or cooling of the structure.

4. A thermal transfer system as in claim 1 including:

a heating or cooling device coupled to and provides heating or cooling of the container and the structure.

5. A thermal transfer system as in claim 1 including:

a plurality of structures in the container.

6. A thermal transfer system as in claim 1, including:

a removable liner configured to cover at least a portion of the structure.

7. A thermal transfer system as in claim 1 wherein:

a volume of the containers in the range from substantially 1 liter to 250 liters.

8. A thermal transfer system as in claim 1 wherein:

a volume of the container is in the range from substantially 250 liter to 10,000 liters.

9. A thermal transfer system as in claim 1 wherein:

the distal end of the structure contacts at least a portion of the interior surface of the container.

10. A thermal transfer system as in claim 1 wherein:

a distance between the distal end of the structure and the interior surface of the container is a non-contacting distance not greater than one inch.

11. A thermal transfer system as in claim 1 wherein:

the container includes a jacket defining an interstitial space positioned between the jacket and a wall of the container for receiving a flow of a heat exchange fluid, the jacket further including a plurality of spiral baffles for enhancing thermal exchange between the heat exchange fluid and the container.

12. A thermal transfer system as in claim 1 wherein:

a heat exchange fluid flows within the structure.

13. A thermal transfer system as in claim 12 wherein:

an interior portion of the structure has baffles.

14. A thermal transfer system as in claim 13 wherein:

the structure is configured to maximize an area of a surface of the structure that is in contact with the medium.

15. A thermal transfer system as in claim 12 wherein:
a heat exchange extension is at least partially coupled to the structure.

16. A thermal transfer system as in claim 1 wherein:
the medium in substantially uniformly heated or cooled.

17. A thermal transfer system as in claim 1 wherein:
the medium is heated or cooled in substantially one direction relative to the structure.

18. A thermal transfer system as in claim 1 wherein:
the structure is positioned to induce a thermal gradient in the medium such that the thermal gradient is in a predetermined direction.

19. A thermal system as in claim 1 wherein:
the medium is heated or cooled in a predetermined direction.

20. A thermal transfer system as in claim 1 wherein:
the medium is heated or cooled such that the thermal gradient is in a predetermined direction.

21. A thermal transfer system as in claim 1 wherein:
the medium is heated or cooled at a predetermined rate.

22. A thermal transfer system as in claim 1 wherein:
the medium is heated or cooled such that the thermal gradient is in a predetermined direction and the heating or cooling occurs at a predetermined rate.

23. A thermal transfer system as in claim 1 wherein:
the medium is a biopharmaceutical product.

24. A thermal transfer system as in claim 1 wherein:
the container has a nonporous bottom.

25. A thermal transfer system as in claim 1 wherein:
the container has nonporous walls.

26. A thermal transfer system as in claim 1 wherein:
the container has a top.

27. A thermal transfer system as in claim 1 wherein:
the container has a nonporous top.

28. A thermal transfer system as in claim 1 including:
a distal portion of the structure configured to improve thermal transport of the thermal transfer bridge.

29. A thermal transfer system as in claim 1 wherein:
the medium includes proteins.

30. A thermal transfer system, comprising:
a container for receiving a medium;
a structure positioned in the container, a heat exchange member at least partially coupled to the structure and extending into the container wherein a distal end of the heat exchange member is placed in close proximity to an interior surface of the container to allow formation of a thermal transfer bridge, by said medium, wherein heat is transferred from said distal end of the heat exchange member through said thermal bridge to said interior wall in response to said interior wall being actively cooled.

31. A thermal transfer system as in claim 30 wherein:

a heating or cooling device is coupled to and provides heating or cooling of the container.

32. A thermal transfer system as in claim 30 wherein:

a heating or cooling device is coupled to and provides heating or cooling of the structure positioned inside the container.

33. A thermal transfer system as in claim 30 wherein:

a heating or cooling device is coupled to and provides heating or cooling of the structure and the container.

34. A thermal transfer system as in claim 30 wherein:

there is a plurality of heat exchange members.

35. A thermal transfer system as in claim 30, further comprising:

a removable liner configured to cover at least a portion of the heat exchange member.

36. A thermal transfer system as in claim 30 wherein:

a volume of the container is in the range from substantially 1 liter to 250 liters.

37. A thermal transfer system as in claim 30 wherein:

a volume of the container is in the range from substantially 250 liter to 10,000 liters.

38. A thermal transfer system as in claim 30 wherein:

the container includes a jacket defining an interstitial space positioned between the jacket and a wall of the container for receiving a flow of a heat exchange

fluid, the jacket further including a plurality of spiral baffles for enhancing thermal exchange between the heat exchange fluid and the container.

39. A thermal transfer system as in claim 30 wherein:
a heat exchange fluid flows within the structure.

40. A thermal transfer system as in claim 30 wherein:
the heat exchange fluid flows into the structure through an interior passage in the structure.

41. A thermal transfer system as in claim 30 wherein:
the heat exchange fluid flows out of the structure through an outer passage in the structure wherein one portion of the outer portion of the outer passage comprises an outer wall of the structure.

42. A thermal transfer system as in claim 30 wherein:
a heat exchange fluid flows within the heat exchange member.

43. A thermal transfer system as in claim 39 wherein:
an interior portion of the structure has baffles.

44. A thermal transfer system as in claim 42 wherein:
an interior portion of the heat exchange member has baffles.

45. A thermal transfer system as in claim 39 wherein:
an interior portion of the portion of the structure extending into the container has baffles.

46. A thermal transfer system as in claim 39 wherein:
the heat exchange fluid flows into the heat exchange member from the structure.

47. A thermal transfer system as in claim 30 wherein:

a heat exchange fluid flows into the heat exchange member from a heat exchange supply line.

48. A thermal transfer system as in claim 38 wherein:

the heat exchange fluid flows does not flow through the distal end of the heat exchange member.

49. A thermal transfer system as in claim 30 wherein:

a distance between the distal end of the heat exchange member and the interior surface of the container is a non-contacting distance not greater than one inch.

50. A thermal transfer system as in claim 30 wherein:

the medium is substantially uniformly heated and cooled.

51. A thermal transfer system as in claim 30 wherein:

the medium is heated or cooled in substantially one direction relative to the structure.

52. A thermal transfer system as in claim 30 wherein:

the medium is heated or cooled at a predetermined rate.

53. A thermal transfer system as in claim 30 wherein:

the medium is heated or cooled such that the thermal gradient is in a predetermined direction and the heating or cooling occurs at a predetermined rate.

54. A thermal transfer system as in claim 30 wherein:
the medium is a biopharmaceutical product.

55. A thermal transfer system as in claim 30 wherein:
the medium includes proteins.